CPSC-IAG-05-1083

05

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

INTERAGENCY AGREEMENT

1. IAG NO. (FDA)	2. TYPE OF AGREEMENT	3. MODIFICATION NO.
224-03-6005	☐ New ☒ Mod2 ☐ Administrative ☐ No Cost Ext.	2

4. TITLE OF PROJECT: Emergency department visits for injuries related to medical devices: data collection and processing to support surveillance.

5. DESCRIPTION OF WORK - ATTACHED	6. AMOUNT	
See Attached	$32,000.00	
7. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY	**LIAISON NAME:**	**PHONE NO.**
Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814	Phil Travers	(301) 504.7447
8. NAME AND ADDRESS OF PARTICIPATING FDA UNIT	**LIAISON NAME:**	**PHONE NO.**
CDRH/OSB/DPS 1350 Piccard Drive, Room 300B Rockville, MD 20850	Donna Schwartz	(301) 594.2805

9. PERIOD OF AGREEMENT — FROM: 10/1/04 — THROUGH: 9/30/05

This agreement may be terminated by either party upon a thirty day advance written notice.

10. AUTHORITY (FDA)
- ☐ Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535
- ☒ Section 301 of the Public Health Service Act (42 USC 241)
- ☐ Other (specify) _____

11. AUTHORITY *(Other Agency)* This agreement is made under the authority of Section 29(c) and 29(e) of the consumer product safety act is U.S.C. 2078 (c) and (e).

12. FDA FUNDING INFORMATION

09523036005DPSX
R-09523 5-6998986 22390L-40
25.38 7550600
927645523

☒ Increase from $0 by $32,000.00 to $32,000.00

☐ Decrease from _____ by _____ to _____

13. Administrative billing requirements will comply with GAO Policy and Procedures, Title 7, Section 8.4

☒ Billing: X OPAC system FDA ALC 75060099 Other Agency ALC 61-00-0001

☐ _____ SF 1080 - FDA Accounting (HFA-120) 5600 Fishers Lane, Rockville, MD 20857

14. PARTICIPATING AGENCY FUNDING INFORMATION *(This block must be completed if funding is being provided to the FDA)*

FOR CPSC: TIN: 520978750 US TREAS. CODE: 6150100
DUNS: 069287522 ACCOUNTING DATA: 05 PS EXOB 4310 11179 252e

a. Legal authority for the acquisition of supplies/services exists within your agency.
b. This action does not conflict with any other agency's authority or responsibility.

15. PARTICIPATING AGENCY IS
- ☒ Required to sign
- ☐ Not required to sign

16. FDA ACCEPTANCE	17. PARTICIPATING AGENCY ACCEPTANCE
NAME: Rosemary Springer	NAME: Donna Hutton
TITLE: Chief Grants Management Officer, FDA	TITLE: CPSC Contracting Officer
DATE: 4/1/05	DATE: 3/25/05

FDA 3443 (2/97)

Interagency Agreement
between the
U.S. Food and Drug Administration,
Center for Devices and Radiological Health
and the
U.S. Consumer Product Safety Commission
224-03-6005
Note: This IAG should be processed expeditiously to allow sufficient time for necessary data collection during this fiscal year.

I. Objective

Under this agreement between the Center for Devices and Radiological Health (CDRH) and the Consumer Product Safety Commission (CPSC), CDRH will contribute to the cost of the National Electronic Injury Surveillance System (NEISS) and CPSC will maintain and add to the current scope of NEISS to accommodate the special interests of CDRH that pertain to the collection of medical device-associated injury data.

II. Background

CPSC contracts with hospital emergency rooms to collect injury data from emergency room records for the system known as NEISS. This system is used by CPSC to identify and measure the magnitude of injury problems associated with consumer products that are treated in hospital emergency departments in the U.S. and its territories. Since 1978, other federal agencies have found it useful to have CPSC expand the scope of injury data collected by NEISS for their purposes. This agreement will enable CDRH to obtain data on adverse events associated with medical devices from NEISS.

III. Statement of Work

Under the terms of this agreement CDRH will contribute funds to offset the cost of NEISS contracts in return for sharing of data from this system.

Under the terms of this agreement CPSC will:

1. Deliver to hospital coders instructional materials for identifying and coding medical device-associated injuries as provided by CDRH and approved by CPSC, including printed instructions, coding examples, background materials, etc.

2. Provide training with CDRH for hospital coders in the abstraction of information from hospital emergency room records of interest to CDRH for the NEISS primary screen.

3. Collect all medical device case primary screen data from October 1, 2004 through September 30, 2005 and provide CDRH with this data.

Clause:

FDA/CDRH plans to continue the project into FY 2006 and will actively pursue continued funding for the project for FY 2006.

IV. Estimated Cost and Conditions of Payment

Under the terms of this agreement funding from CDRH will be paid to CPSC in FY 2005 immediately upon receipt of the signed interagency agreement and billing statements.

$32,000.00

V. Information Safeguards

CDRH shall comply with the Privacy Act in using and storing information related to this agreement. CDRH agrees that the identity of any injured person, and of any person who treated an injured person, shall not, without the consent of person identified, be included in any report of information made available by CDRH to any of the public. CDRH also agrees that it shall not disclose information compiled under this agreement to the public if the information describes a consumer product in such a manner that will permit the public to ascertain readily the identity of the manufacturer or private labeler unless the Commission is notified, and the Commission complies with Section 6(b) of the CPSA (15 U.S.C. 2055).

VI. Method of Payment

FDA/CDRH agrees to contribute $32,000.00 to the cost of the NEISS to accommodate CDRH plans as specified herein in fiscal year 2005 upon billing through the OPAC system. Upon receipt of OPAC statement, FDA/CDRH will make payment to:

CPSC: Debbie Hodge
Director of Division of Finance, CPSC
4330 East West Highway, Rm 522-A
Bethesda, MD 20814-4408

Special Program Clearances & Approval Checklist

Introduction: The following checklist must be attached to each Memorandum of Need submitted to the Contracting Officer. The applicability of these clearances is discussed in the DHHS Project Officers' Contracting Handbook. The Project Officer must indicate which of the clearances apply, if any.

MON No. _____

Applicable	Not Applicable	Part A - Special Clearances/Approvals Required Prior to Approval of the MON
_____	_____x_____	1. ADP Systems Security - Handbook
_____	_____x_____	2. Approval for Providing Government Property
_____	_____x_____	3. Approval of Contracts with Present or Former Federal Employees
_____	_____x_____	4. Approval of Contracts with State Governments
_____	_____x_____	5. Approval of Studies on Fraud, Abuse, and Waste in FDA Programs
_____	_____x_____	6. Audiovisual (videotape, television and motion picture) Production Approval
_____	_____x_____	7. Classified Contracts Clearance
_____	_____x_____	8. Clearance for Release of Privileged Information to Contractors
_____	_____x_____	9. Commercial or Industrial Products or Services Clearance (A contract vs. in-house performance review and determination pursuant to OMB Circular A-76)
_____	_____x_____	10. Environmental Impact Determination
_____	_____x_____	11. Evaluation Contracts - Handbook
_____	_____x_____	12. Good Laboratory Practices
_____	_____x_____	13. Information Technology
_____	_____x_____	14. Micrographics Approval
_____	_____x_____	15. Paid Advertising Approval
_____	_____x_____	16. Paperwork Reduction Act
_____	_____x_____	17. Printing Services Clearance - Handbook
_____	____ x_____	18. Privacy Act (P.O. 93-579) Systems of Records Determination
_____	_____x_____	19. Public Advisory Committee Approval - Handbook
_____	_____x_____	20. Public Affairs Services
_____	_____x_____	21. Publications Approval
_____	_____x_____	22. Safety and Health Approval for Contracts Involving Hazardous Substance - FDA Safety Officer
_____	_____x_____	23. Senior Management Review
_____	_____x_____	24. Scientific Review
_____	_____x_____	25. Training Contracts Clearance

Part B - Clearances/Approvals Required Prior to Contract Award

_____	_____x_____	1. Animal Welfare Approval
_____	_____x_____	2. Approval for Projects Involving Human Subjects
_____	_____x_____	3. EEO (over $1,000,000)
_____	_____x_____	4. Foreign Research Contract Clearance

The above indicated clearances apply to the acquisition and the appropriate clearance documents are attached or action has been initiated to obtain them.

_____ Contract Coordinator

_____Brockton Hefflin, MD, MPH, DPS_____ Project Officer

B. Hefflin